The chlorine industry is desperate to avoid a ban on PVC plastic (also known as polyvinyl chloride, or simply "vinyl") but it's going to be an uphill battle.

Many chlorine-containing chemicals are toxic and long-lived and they tend to concentrate as they move up the food chain. Therefore, as the 20th century draws to a close, many high-volume chlorinated chemicals have already been phased out in countries around the world, and many more are under growing pressure:

** Chlorinated pesticides such as DDT, toxaphene, chlordane and heptachlor have been banned in many countries because they are toxic and long-lived and they kill creatures they were never intended to kill.

** PVC products, the Vinyl Institute initiated a $1 million ad campaign in 1999, highlighting the use of PVC in medicine.[2] The pro-PVC ads ran on TV, in the WASHINGTON POST, and in ROLL CALL (a newspaper circulated mainly on Capitol Hill in Washington, D.C.). The ads depict a group of doctors and nurses in an operating room, along with PVC equipment such as intravenous (IV) bags, tubing and respiratory equipment. The ad explains that "medical professionals have placed their trust in one material time and time again: vinyl."[3]

Although PVC medical products comprise only 6% of the total North American PVC market, one quarter of all plastic medical products are made of PVC, including most IV bags and tubing.[4] Common PVC medical devices include IV and blood bags, tubing, gloves, catheters, ID bracelets, endotracheal tubes, feeding bags and other equipment.

The Vinyl Institute's ads did little to quiet public concerns about vinyl. Instead, they provoked action by a large and growing coalition of public health advocates -- the Health Care Without Harm campaign.[5]

Health Care Without Harm (HCWH) adapted its name from the Hippocratic Oath -- the ethical creed of the medical profession which obliges doctors and other practitioners to "first, do no harm."

HCWH had previously identified PVC as the major culprit in the generation of dioxin from medical waste incinerators, one of the largest sources of dioxin in the U.S.[6] In 1996, Physicians for Social Responsibility and other HCWH members convinced the American Public Health Association -- the country's largest association of public health professionals -- to call for a phase-out of PVC in medical devices because PVC generates dioxin when burned. Dioxin is a potent immune system poison, causes cancer in humans and other animals, and interferes with the hormone systems of mammals and other creatures.[7]

Similar resolutions seeking a ban on medical uses of PVC have been passed by the Chicago Medical Society, the Minnesota Medical Association, the California Medical Association and the American Nurses Association.[8]

PVC is unique in the polymer world because it requires large quantities of additives to achieve specific qualities. PVC is a relatively rigid and brittle polymer, so flexibility is achieved through the addition of plasticizers. Other polymers can be made more or less flexible through the rearrangement of polymer chains or by mixing different polymers together, thus eliminating the need for plasticizers. Approximately 90% of the plasticizers produced globally end up in flexible PVC products. While there are numerous plasticizers on the market, the largest group, accounting for more than 69% of U.S. consumption, are the phthalate esters. The phthalate most commonly used in the production of PVC medical devices is Di-(2-ethylhexyl) phthalate, also known as DEHP.

Earlier this year, Health Care Without Harm (HCWH) issued a health alert about the leaching of phthalates from IV bags.[9] HCWH also asked the Center for Sustainable Production at the University of Massachusetts Lowell to evaluate the health risks associated with human exposure to DEHP, as well as alternatives to its use.[10]

The toy industry stopped using DEHP in 1986, shortly after the U.S. EPA [Environmental Protection Agency] listed it as a probable human carcinogen.[11]

Independent laboratory tests conducted for Greenpeace in early 1999 found that medical devices contain up to 81% (by weight) DEHP.[12] By law, toys such as teething rings have been limited to less than 3% DEHP, and U.S. FDA [Food and Drug Administration] limits plasticizers in food containers to 30%.[13] However there are no FDA restrictions on DEHP content or releases into the body from PVC medical devices.

DEHP has been found to leach from IV bags, blood bags, tubing (endotracheal and transfusion) and catheters into solutions, blood products, and eventually into the human body.[14] Of greatest concern is exposure to premature infants, hemophiliacs, and dialysis patients, who suffer from compromised immune and metabolic systems, have long term exposure to DEHP, or are exposed at critical junctures in development.

Some drugs -- especially those with fatty components -- accelerate the DEHP leaching process. Taxol (used to treat breast cancer, ovarian cancer, and AIDS-related Kaposi's sarcoma) is one of the drugs with these characteristics.

Taxol's instructions for intravenous administration include this paragraph: "Contact of the undiluted concentrate with plasticized polyvinyl chloride (PVC) equipment or devices used to prepare solutions for infusion is not recommended. In order to minimize patient exposure to the plasticizer DEHP, which may be leached from PVC infusion bags or sets, diluted Taxol solutions should preferably be stored in bottles (glass, polypropylene) or plastic bags (polypropylene, polyolefin) and administered through polyethylene-lined administration sets."[15]

The two IV manufacturers with about 80% of the U.S. market, Abbott Laboratories and Baxter Healthcare, print warnings about the leaching of DEHP into a variety of solutions. The literature that accompanies Baxter's Viaflex container, for instance, advises that...
"solutions in contact with the plastic container can leach out certain of its chemical components in very small amounts within the expiration period, e.g., di-2-ethylhexyl phthalate (DEHP) up to 5 parts per million."[16] As a 1994 article in the JOURNAL OF INTRAVENOUS NURSING warns, printed instructions are not enough: hospital staff may not be aware that DEHP leaches from PVC IV products, and may not routinely read package literature that directs the use of non-vinyl products.[17]

The Lowell Center’s review examined the published literature on animal laboratory studies, in-vitro studies in human and animal cell lines, and available human exposure studies. It found evidence that DEHP or its metabolite MEHP can affect the testes, ovaries, kidneys, liver, circulatory system, pulmonary system and heart.

There is consensus that DEHP causes a wide range of adverse impacts in experimental animals, including cancer, testicular atrophy, and cardiac toxicity. However, the relevance of these results to humans is disputed. No long-term human studies have been conducted. Nevertheless, many animal studies demonstrate health effects from DEHP at exposure levels documented in people who receive many blood transfusions, kidney dialysis patients and high risk newborn babies:

** Hemodialysis patients may be exposed to 10 to 20 times more DEHP than the levels that caused liver damage in rhesus monkeys.[18]

** A hemorrhaging patient may receive more DEHP from PVC blood bags and tubing than the equivalent amount that significantly reduced the heart rate of rats.[19]

** An infant receiving Extracorporeal Membrane Oxygenation (ECMO) therapy with PVC tubing may be exposed to more DEHP than the level that damaged the testes of immature rats.[20]

Given the evidence of adverse effects of DEHP in laboratory animals, evidence of human exposure, limited evidence of health effects in humans, and uncertainty regarding the mechanism by which these effects occur, it is clearly prudent to take a precautionary approach to the health risks posed by DEHP in medical devices.

The precautionary approach is receiving critical attention from the public health community, which is why the PVC-in-medicine issue has galvanized a huge industry backlash. More next week.

--by Charlie Cray

[1] For a detailed list of restrictions and bans on PVC toys and other products see Greenpeace International’s web site: http://-